# 510(k) Summary of Safety and Effectiveness

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K011267

**Applicant Information:**

| | |
|---|---|
| Date Prepared: | January 17, 2001 |
| Name: | Broncus Technologies, Inc. |
| Address: | 1400 N. Shoreline Blvd.<br>Building A, Suite 8<br>Mountain View, CA 94043 |
| Contact Person: | Timothy R. Williams |
| Phone Number: | 650-428-1600 ext.312 |
| Fax Number: | 650-428-1542 |

**Device Information:**

| | |
|---|---|
| Classification: | Class II |
| Trade Name: | Exhale™ RF Probe |
| Classification Name: | Bronchoscope and Accessories 21 CFR 874.4680 |

**Equivalent Devices:**

The subject device is substantially equivalent in intended use and/or method of operation to the following predicate devices:

| | |
|---|---|
| Broncus Technologies, Inc. | Broncus™ Coagulation Electrode System |
| Olympus America Inc. | Coagulation Electrode |

**Description:**

The *Exhale* RF Probe is a catheter that delivers radiofrequency energy to the desired target site. The tip of the catheter has an optional use shoulder that can be deployed to assist the user in maintaining the position of the catheter tip at the target site.

**Intended Use:**

The *Exhale* RF Probe is intended for electrosurgical procedures (i.e. coagulation/cauterization, hemostasis, etc.), through a bronchoscope in the upper airways and tracheobronchial tree.

**510(k) Summary of Safety and Effectiveness, continued**

**Comparison to Predicate Devices:**

The *Exhale* RF Probe is substantially equivalent in intended use and/or method of operation to the named predicate devices.

The similarities and differences in the indications for use and methods of operation between the subject device and the legally marketed devices to which equivalency is claimed are detailed in Table 1.

**Table 1. Device Similarities and Differences**

| | [redacted] | [redacted] | [redacted] |
|---|---|---|---|
| Indications for Use | Broncus Coagulation Electrode System | Both devices are intended to perform electrosurgical procedures such as hemostasis or coagulation in the tracheobronchial tree. | The *Exhale* RF probe also is indicated for use in the upper airways. The *Exhale* RF probe is also indicated for any electrosurgical procedure. |
| | Olympus America Coagulation Electrode | Both devices are intended to perform electrosurgical procedures such as coagulation or hemostasis in the tracheobronchial tree and upper airways. | None |
| Method Of Introduction | Broncus Coagulation Electrode System | Both devices are introduced through the 2mm working channel of a bronchoscope. | None |
| | Olympus America Coagulation Electrode | Both devices are introduced into the upper airways or tracheobronchial tree via a scope. | The *Exhale* RF probe is designed for use with a bronchoscope, while the Olympus America Device is designed for use with an endoscope. |

**Table 1. Device Similarities and Differences (continued)**

| | | | |
|---|---|---|---|
| Method of Effecting Treatment | Broncus Coagulation Electrode System | Both devices use heat to facilitate treatment. | The Broncus Coagulation Electrode System uses an expandable metal basket, while the *Exhale* RF Probe uses a distal tip electrode. |
| | Olympus America Coagulation Electrode | Both devices use heat delivered via a distal tip electrode to facilitate treatment. | None |
| Method of Heating | Broncus Coagulation Electrode System | Both devices use monopolar RF energy | None |
| | Olympus America Coagulation Electrode | Both devices use monopolar RF energy | None |
| Method of Stabilizing Electrode at Target Site | Broncus Coagulation Electrode System | Both devices rely on user experience and expertise to place and maintain the electrode at the target site, without causing damage to adjacent structures. | The *Exhale* RF Probe also has an optional shoulder that can be used to assist the user in maintaining the correct position of the electrode at the target site during treatment. |
| | Olympus America Coagulation Electrode | Both devices rely on user experience and expertise to place and maintain the electrode at the target site, without causing damage to adjacent structures. | The *Exhale* RF Probe also has an optional shoulder that can be used to assist the user in maintaining the correct position of the electrode at the target site during treatment. |

**Non-Clinical Test Results:**

*Performance*
The *Exhale* RF Probe has undergone and passed functional and electrical testing designed to assess the performance of the catheter.

*Biocompatibility*
The materials used in the *Exhale* RF Probe have proven biocompatibility.

**Summary of Substantial Equivalence:**

Based on the intended use and product performance information provided in this notification, the subject device has been shown to be substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 8 2001

Broncus Technologies, Inc.
c/o Mark Job
TUV Product Services
1775 Old Highway 8
New Brighton, MN 55412-1891

Re: K011267
Trade Name: Exhale™ RF Probe
Regulatory Class: 874.4680
Product Code: 77EOQ
Dated: April 23, 2001
Received: April 26, 2001

Dear Mr. Job:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-6413. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) Number (if known): K011267

Device Name: Exhale™ RF Probe

Indications for Use:

The Exhale RF™ Probe is intended for electrosurgical procedures (i.e., coagulation/cauterization, hemostasis, etc.) through a bronchoscope in the upper airways and tracheobronchial tree.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

**Prescription Use**
**(Per 21 CFR 801.109)**

(Optional Format 3-10-98)

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K011267